

REMARKS/ARGUMENTS

Claims 14-37 are active in this application. Support for Claims 34-37 is found in the paragraph bridging pages 3 and 4. Claims 25 and 33 are amended to more clearly set forth the claimed invention. No new matter is added.

Applicants thank the Examiner for indicating that Claims 22, 23, 30, and 31 are allowable. In view of the following remarks, Applicants request reconsideration of the rejections and allowance of all of the pending claims.

**Applicants again request that the Examiner return an initialed and signed copy of the PTO form 1449 filed as an Information Disclosure Statement (IDS) on February 14, 2002 in the next communication from the Patent Office. For convenience a copy of that IDS is attached.**

The present invention is based on the discovery that certain types of viable lactobacilli have a positive effect on human intestinal mucosa and are therefore particularly useful for a sports drink “which in addition to a nutrient and fluid supplementation before or after physical activity in order to build up and recover, respectively, the energy and fluid levels of the body, also relieves the symptoms of stress.” (page 3, lines 1-4 of the present application; see also Claims 14 and 15).

As described in the application on page 3, “It has now been surprisingly been shown that viable lactobacilli can be mixed with micronutrients, carbohydrates, salts and proteins, without negative effects on e.g. antioxidants, to a beverage having a good taste and a good shelf-life.” In addition, the claims provide the use of this sports drink for treating stress symptoms, gastrointestinal disturbances and lesions of the mucosal membrane of the intestine.

The claimed invention is not described in the cited prior art because the cited prior art provides no description for selecting those lactobacilli having a positive effect on human intestinal mucosa and their incorporation into a sports drink as outlined above.

The rejection of Claim 14 under 35 U.S.C. § 103(a) over Strawberry Yogurt drink, Tamine and Yakult is untenable for the following reasons.

The basic premise of this rejection is that Claim 14 is not patentable because beverages containing yogurt, which in turn contains lactic acid bacteria were known. However, the combined publications fail to provide any suggestion or motivation to select those lactobacilli that have a positive effect on human intestinal mucosa. One example of such an effect is described on page 3 of the application: “by initiating the production of mucin or short chain fatty acids.”

In effect, the prior art describes a large genus while the present claims provide a specific subgenus having the aforementioned properties. Applicants direct the Examiner’s attention to MPEP § 2144.08 which states, in part: “The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a prima facie case of obviousness. *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994).” Also, Applicants further note “[t]he prior art disclosure may be express, implicit, or inherent. Regardless of the type of disclosure, the prior art must provide some motivation to one of ordinary skill in the art to make the claimed invention in order to support a conclusion of obviousness.” (MPEP § 2144.08). Here, the prior art does not provide the requisite suggestion or motivation to select those lactobacilli that have a positive effect on human intestinal mucosa. Therefore, Claim 14 would not have been obvious in view of the cited publications and as such withdrawal of this ground of rejection is requested.

Claims 15 and 33 are rejected for the same basis as Claim 14 above and further in view of WO 98/46091 (“Kurpa”). This rejection is also untenable.

The deficiencies of Strawberry Yogurt drink, Tamine and Yakult are discussed in detail above. Kurpa merely describes a sports drink containing micronutrients. Therefore, when Kurpa is combined with Strawberry Yogurt drink, Tamine and Yakult, the combined publications fail to provide any suggestion or motivation to select those lactobacilli that have a positive effect on human intestinal mucosa. Withdrawal of this ground of rejection is requested.

Concerning the methods set forth in Claims 25 and 33, the combination of prior art fails to provide the requisite description to support a *prima facie* case of obviousness. The Court of Appeals of the Federal Circuit, has stated most recently<sup>1</sup> in *Jansen v. Rexall Sundown, Inc.* (68 U.S.P.Q. 2d 1154), “in need thereof” language is not satisfied if the active ingredient is administered for a purpose other than the claimed purpose. In *Jansen*, the Court held that treating a patient “**in need thereof**” with the goal of treating a macrocytic-megaloblastic anemia distinguishes the claim from what was known previously. In particular, it is also noted that based on the treatment of an individual “in need thereof,” the Patent Office granted claims over prior art that taught the combination of folic acid and vitamin B<sub>12</sub> for purposes other than the claimed method.

The situation in the present application is similar to the situation presented to the Court in *Jansen*. Here, the prior art describes a beverages containing generally any lactic acid bacteria but do not describe the particular lactobacilli claimed nor the administration of the beverage for the purpose of treating stress symptoms, gastrointestinal disturbances, and lesions of the mucosal membrane as claimed. Withdrawal of this ground of rejection is requested.

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<sup>1</sup> Following a series of cases from the C.A.F.C. and the C.C.P.A., namely *Rapoport v. Dement*, 59 U.S.P.Q.2d 1215 (Fed. Cir. 2001); *In re Marshall*, 198 U.S.P.Q. 344, 346 (CCPA 1978); and *In re Shetty*, 195 U.S.P.Q. 753, 252 (CCCPA 1977).

The rejection of Claims 16-21, 26-29 and 32 under 35 U.S.C. § 103(a) over the above references and further in view of WO 89/08405 ("Mollin") is also untenable for the following reasons.

The deficiencies of Strawberry Yogurt drink, Tamine and Yakult are discussed in detail above. Mollin describes a health drink for horses containing various nutrients and lactobacilli (see page 2, lines 11-17). However, the combined publications fail to provide any suggestion or motivation to select those lactobacilli that have a positive effect on human intestinal mucosa. In fact, Mollin describes that the lactobacilli useful for the invention must meet certain characteristics to be suitable for the administration to horses (page 3, line 23 to page 4, line 13) but does not describe anything regarding positively effecting human intestinal mucosa. Therefore, Claims 16-21, 26-29 and 32 would not have been obvious in view of the cited publications and as such withdrawal of this ground of rejection is requested.

Finally, the rejection of Claim 24 under 35 U.S.C. § 103(a) over the above references and further in view of WO98/05343 ("Masuyama") is untenable for the following reasons.

As discussed in detail above, the cited publications fail to provide any suggestion or motivation to select those lactobacilli that have a positive effect on human intestinal mucosa. Masuyama merely describes freeze drying lactobacilli and formation into tablets. However, Masuyama does not add anything to the above cited references with respect to the selection of particular lactobacilli having a positive effect on human intestinal mucosa. Therefore, Claim 24 would not have been obvious in view of the combination of cited publications. Withdrawal of this ground of rejection is requested.

Application No. 09/926,586

Reply to Office Action of November 17, 2003.

Applicants request allowance of this application.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read 'DJP', is written over a horizontal line.

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